MAY 1 7 2000

K000405

510(K) SUMMARY FOR THE INTERCURE LTD. RESPI-LOW

Submitter's Name, Address, Telephone Number, and Contact Person

InterCure Ltd.
Communication Park
Neve-Ilan 90850, Israel

Contact: Dr. Benjamin Gavish
President, InterCure Ltd.
Phone: 972-2-5337747
Facsimile: 972-2-5700495

Date Prepared: May 4, 2000

Name of the Device

Respi-Low

Common or Usual Name

Biofeedback Device

Predicate Devices

1. Ultramind International's Ultramind Biofeedback System with de-STRESS Software (K980373);
2. Chattanooga Group, Inc.'s EMG Retrainer (K972487);
3. Hemodynamics, Inc.'s Leunomed RFB 5000 (K881164);
4. Thought Technology's Calmtone and Calmpute (K834519); and
5. BioResponse's Relax-A-Tone (K780436).

Intended Use

The Respi-Low is intended for use as a relaxation treatment for the reduction of stress by leading the user through interactively guided and monitored

breathing exercises. The device is indicated for use as an adjunctive treatment for high blood pressure under the direction of a healthcare professional, together with other pharmacological and/or non-pharmacological interventions as prescribed by the physician.

Principles of Operation/Technical Characteristics

The Respi-Low is a hand-held, battery operated device containing a respiratory muscle activity monitor (respiration sensor), a computerized control unit, and headphones to provide feedback to the user. In order to reduce high blood pressure, the Respi-Low guides the user to slow and modify his/her breathing pattern using the natural tendency of the human body to follow external rhythms. The breathing pattern modification occurs as the user voluntarily follows the sound pattern with his/her breathing movements. The device is fully interactive, as the musical pattern is designed in response to the user's last five breaths. Thus, the pattern is gradually modified to attempt to extend expiration and slow the breathing rate. If the user's breathing does not slow to match the music, the device returns to the user's previous breathing pattern/rate, and again begins to gradually modify the pattern to pull the user's breathing down to the desired rate. This process reaches a steady state at the lowest breathing rate convenient to the user.

Summary of the Basis for the Finding of Substantial Equivalence

The Respi-Low is substantially equivalent to a number of other biofeedback devices that have previously been cleared for use in relaxation training

and/or stress reduction, including: (1) Ultramind International's Ultramind Biofeedback System with de-STRESS Software (K980373); (2) Chattanooga Group, Inc.'s EMG Retrainer (K972487); (3) Hemodynamics, Inc.'s Leunomed RFB 5000 (K881164); (4) Thought Technology's Calmtone and Calmpute (K834519; and (5) BioResponse's Relax-A-Tone (K780436). All of these devices share the same general intended use in relaxation and/or stress reduction and substantially similar indications for use. Based on extensive clinical testing, the Respi-Low has the extended claim for use as an adjunctive treatment for the reduction of high blood pressure. This difference in the specific indications for use of the Respi-Low compared to the predicates, however, does not raise new questions of safety or efficacy and does not alter its therapeutic effect. The claim is fully supported by the clinical study data. Moreover, the principles of operation and technological characteristics of the Respi-Low are substantially similar to the predicates. Therefore, the devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2000

InterCure, Ltd.
c/o Mr. Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004

Re: K000405
Trade Name: Respi-Low Biofeedback Device
Regulatory Class: II
Product Code: HCC
Dated: February 7, 2000
Received: February 7, 2000

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K000405

Device Name: InterCure Ltd. Respi-Low

Indications for Use:

The Respi-Low is intended for use as a relaxation treatment for the reduction of stress by leading the user through interactively guided and monitored breathing exercises. The device is indicated for use only as an adjunctive treatment for high blood pressure under the direction of a physician, together with other pharmacological and/or non-pharmacological interventions as prescribed by the physician.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-off)

510(k) Number K000405

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

Diana R. Lochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000405